

REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

The phrase “in combination” has been deleted from claim 1 to clarify the invention.

The rejection of the claims under 35 USC 112, second paragraph is thus deemed to be overcome.

Claim 18 has been amended to correct the dependency upon claim 1 and to delete the term “combined”.

Claims 1, 4-5, 12, 14 and 18-24 are rejected under 35 USC 103 as being unpatentable over Patel et al. US ‘052 in view of Scott et al. US ‘307. This ground of rejection is respectfully traversed.

Scott et al. (US 6,887,307) relates to an improved pullulan capsule. The invention of Scott et al. is based on the findings that an addition of hydrocolloids or a hydrocolloid mixture defined as a setting system to a pullulan solution confers an appropriate setting ability with cooling to the pullulan solution so that hard pullulan capsules can be produced with a conventional dip moulding process (column 2, line 64 to column 3, line 24). In addition, Scott et al. describe “the pullulan composition has in aqueous solution a sufficient setting ability” (column 3, lines 48-50). That is, Scott et al. discloses a special pullulan capsule.

On the other hand, the pullulan capsule used in the present invention is not limited as far as it is a capsule comprising a water-soluble polysaccharide as the main component which is stable in a low moisture state and has pH independent disintegration properties (page 10, lines 1-7 in the specification). That is, the pullulan capsule used in the present invention is a common pullulan capsule.

In Scott et al. the pullulan composition has an aqueous solution a sufficient setting ability, whereas in the present invention a capsule preparation preferably is quickly dissolved independently of pH (page 3, lines 8-10; page 8, line 25 to page 10, line 1; and page 11, lines 5-16).

Therefore, it is considered that the pullulan capsule in the present invention differs from the pullulan capsule in Scott et al. The present invention using the common pullulan capsule is not obvious over Scott et al. disclosing the special pullulan capsule.

Moreover, Patel et al. (US 2005/0181052) relates to a microtablet comprising lansoprazole and a lubricant and having an enteric coating wherein the microtablet is free of an intermediate layer between the medicine and the enteric coating and of an alkaline reacting compound (paragraph (0010)). As described in the paragraph (0002) in Patel et al., proton pump inhibitors such as lansoprazole are known to be unstable to acids.

However Scott et al. requires use of acidic surfactants in the setting system (see claims, the Examples, and column 5, lines 5-23).

Therefore, one skilled in the art would not have been motivated to modify the microtablet of Patel et al. containing acid unstable lansoprazole with the special pullulan capsule of Scott et al. containing an acid component.

The USPTO has made clear that "[i]f [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." See MPEP section 2143.01 V, citing *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984). Additionally, section 2143.01 VI of the MPEP plainly states: "The proposed modification cannot change the principle of operation of a reference. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." See also *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Furthermore, according to the USTPO guidelines, "[i]t is improper to combine references where the references teach away from their combination." See MPEP § 2145, citing *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983); see also *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 (Fed.Cir. 2001) ("It is well-established that references which "teach away" cannot serve to create a *prima facie* case of obviousness.") (citations omitted).

Additionally, the claimed invention relates to a capsule preparation containing at least two solid preparations having different medicine release properties wherein the solid preparation is selected from granule or fine granule.

Patel et al. and Scott et al. do not teach or suggest this feature of the claimed invention, even if they are combined.

Thus, the present invention is not obvious over Scott et al. and Patel et al.

In summary, it is respectfully submitted that the claimed invention as amended is not obvious from the combination of references. Accordingly, reconsideration and allowance is solicited.

Respectfully submitted,

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